

### **REMARKS**

Claims 1- 24 are pending in the application. By this Amendment, claims 1, 9, 17 and 22 have been amended. Reconsideration of the previously rejected claims and favorable action is requested in light of the above amendments and the following remarks.

The Office Action objects to claims 1 and 22 for informalities. Claim 9 is rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The Office Action rejects claims 1-4, 6 and 9-24 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,432,040 to Meah (hereafter “Meah”). The Office Action also rejects claims 5 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Meah in view of U.S. Patent No. 6,547,801 to Dargent et al. (hereafter “Dargent”). Finally, the Office Action rejects claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Meah in view Dargent and further in view of U.S. Patent No. 5,944,751 to Laub (hereafter “Laub”). Insofar as these grounds for rejection apply to the present claims, Applicant respectfully traverses.

### **Objections**

Claims 1 and 22 have been amended to correctly recite the term “inflatable” in place of “inflation.” Thus, Applicant requests withdrawal of the objections to claims 1 and 22.

### **Rejections**

Claim 9 has been amended so as not to recite non-statutory subject matter, thus obviating the rejection of that claim under 35 U.S.C. § 101.

### **The Meah Reference**

The Office Action rejects claims 1-4, 6 and 9-24 as anticipated by Meah.

As described in the Abstract, Meah relates to an implantable esophageal sphincter apparatus with an adjustable band to be placed at the lower part of the esophagus. The inflation of the band, or sphincter body, can be increased or decreased to adjust the tightness of the device. Meah teaches 3 mechanisms for inflation of the band: (1) fluid is inserted into or withdrawn from a chamber with a syringe; (2) a bi-directional fluid pump that pumps fluid from/to a reservoir; and (3) a manually controlled pump implanted beneath the skin. See Meah, col. 5,

lines 29 through col. 6, line 28.

To establish a prima facie case of anticipation under 35 U.S.C. § 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. MPEP 2131. Applicant respectfully submits that this criterion has not been met for Meah as applied to the claims 1-4, 6 and 9-24 of the present invention.

For example, claim 1 of the present invention recites, in part, a gastric banding apparatus comprising “a *passive pressurized fluid reservoir* for providing fluid to inflate said inflatable chamber....” Meah, in contrast with the claimed invention, does not include a passive reservoir. Meah discloses use of a variety of active devices, such a pumps or syringes, to alter pressure sufficient to inflate (or deflate) a band. As noted in the present specification, the use of a passive reservoir provides advantages over mechanically pressurized systems. For example, paragraph 0035 states: “Because this system uses a pressurized reservoir rather than a mechanical pressurization means (i.e. a pump or screw), the present system is more energy-efficient than those disclosed in the existing remote-controlled adjustable gastric band systems.... Power is only required when operating the valves 31 and/or 32, and then only for relatively short time intervals.” Similar to the systems disclosed in the specification that use mechanical pressurization means, Meah discloses use of active pressurization systems not applicable to the present invention. Applicant respectfully submits that Meah does not anticipate claim 1 for at least this reason. Thus, withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(e) is respectfully requested.

Claims 2-4, 6 and 9-16 depend directly or indirectly from claim 1 and incorporate all the features recited therein. Thus, these claims are distinguishable over Meah for at least the reasons recited above with respect to claim 1.

Claim 17 of the present invention recites, in part, “a first valve, between a pressurized fluid reservoir and said inflatable chamber ... wherein the pressure in said pressurized fluid reservoir remains greater than or equal to the pressure in said inflatable chamber.” As applied in the Office Action to claim 17, Meah teaches a bi-directional pump as a “first valve” located between a fluid reservoir and inflatable chamber. In contrast with claim 17, the bi-directional pump of Meah would inherently alter the pressure of the fluid reservoir and/or the inflatable

chamber such that, for at least a period of time, the pressure in the fluid reservoir is less than that of the inflatable chamber. Applicant respectfully submits that Meah does not anticipate claim 17 for at least this reason. Thus, withdrawal of the rejection of claim 17 under 35 U.S.C. § 102(e) is respectfully requested.

Claims 18-21 depend directly from claim 17 and incorporate all the features recited therein. Thus, these claims are distinguishable over Meah for at least the reasons recited above with respect to claim 17.

Claim 22 of the present invention recites, in part, “a reservoir for providing pressurized fluid to inflate said inflatable member, said reservoir having a pressure that remains greater than or equal to the pressure in said inflatable chamber.” As applied in the Office Action to claim 22, Meah teaches a mechanical inflation device comprising a one-way valve between a fluid reservoir and an inflatable chamber. As is clearly shown in the text and figure of Meah cited in the Office Action, the pressure of the fluid reservoir must be less than that of the inflatable chamber after inflation of the chamber. Applicant respectfully submits that Meah does not anticipate claim 22 for at least this reason. Thus, withdrawal of the rejection of claim 22 under 35 U.S.C. § 102(e) is respectfully requested.

Claims 23-24 depend directly or indirectly from claim 22 and incorporate all the features recited therein. Thus, these claims are distinguishable over Meah for at least the reasons recited above with respect to claim 22.

Thus, withdrawal of the rejection of claims 1-4, 6 and 9-24 under 35 U.S.C. § 102(e) is respectfully requested.

#### Meah in view of Dargent

The Office Action rejects claims 5 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Meah in view of Dargent.

Dargent teaches a gastric constriction device. As applied in the Office Action, Dargent teaches an induction coil located within a receiver and connected to an electrolyte capacitor to store, charge and provide power for the receiver to actuate and drive a motor.

To establish a prima facie case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be some expectation of success. Third, the prior art references must disclose or suggest all of the claimed features. MPEP 2143. Applicant respectfully submits that these criteria have not been met for Meah in view of Dargent as applied to claims 5 and 7 of the present invention.

Claims 5 and 7 depend indirectly from claim 1 and incorporate all the features recited therein. As noted above, Meah fails to teach or suggest all the features of claim 1. Specifically, Meah does not disclose “a passive pressurized fluid reservoir for providing fluid to inflate said inflatable chamber.” Dargent does not supply the deficiency of Meah by disclosing a gastric constriction device employing a constricting flexible band. In fact, Dargent does not disclose any use of a pressurized reservoir. Because claims 5 and 7 incorporate all the elements of claim 1, Applicant respectfully submits that Meah and Dargent, alone or in combination, fail to disclose or suggest all of the features of claims 5 and 7. Thus, withdrawal of the rejection of claims 5 and 7 under 35 U.S.C. § 103(a) is respectfully requested.

Meah in view of Dargent and Laub

The Office Action rejects claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Meah in view of Dargent and further in view of Laub.

Laub discloses a vibratory heart valve. As applied in the Office Action, Laub teaches that energy generated by movement of an electromechanical valve supplies a small current through piezoelectric means to power an oscillator.

Claim 8 depends indirectly from claim 1 and incorporates all the features recited therein. As noted above, Meah and Dargent fail to teach or suggest all the features of claim 1. Specifically, Meah and Dargent do not disclose “a passive pressurized fluid reservoir for providing fluid to inflate said inflatable chamber.” Laub fails to supply this deficiency, since Laub also does not disclose a pressurized reservoir. Thus, withdrawal of the rejection of claim 8 under 35 U.S.C. § 103(a) is respectfully requested.

Conclusion

In view of the foregoing, Applicant respectfully requests that the Examiner enter the above-noted amendments before the application is examined upon the merits, and that the above remarks be fully considered in conjunction therewith. Timely allowance of all currently pending claims and the issuance of a Notice of Allowance are requested.

Applicant has filed this Response and Amendment without increasing the number of claims above the number previously submitted or paid for. Accordingly, no additional claims fees are believed to be due at the present time. If such fees or any other fees associated with the filing of this paper are due at this time, please charge the fees to our Deposit Account No. 50-1349. Also, please credit any overpayments to Deposit Account No. 50-1349.

The Examiner is invited to contact Applicant's undersigned representative via telephone if such would expedite prosecution of this application toward allowance.

Respectfully submitted,

Dated: April 16, 2007

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